

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA and
STATE OF NEW JERSEY,

Plaintiffs,

v.

No. 2:17-cv-04540-WB

DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; EUGENE SCALIA, *in his official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA.

Defendants.

**MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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INTRODUCTION

Under the Women’s Health Amendment to the Affordable Care Act, the Health Resources and Services Administration (HRSA), a component of the Department of Health and Human Services, is charged with creating guidelines that define the preventive services that are necessary for women’s health. 42 U.S.C. § 300gg-13(a)(4). Since HRSA released the first version of the Women’s Preventive Services Guidelines (“Guidelines”) in 2011, they have included all “Contraceptive methods and counseling” that have been approved by the Food and Drug Administration. *See* J.A. 311 (2011 Guidelines), 312-A (2019 Guidelines).

Group health plans and health insurance issues must cover the services identified in the Guidelines without imposing a cost-sharing obligation on the part of the insured. 42 U.S.C. § 300gg-13(a). But, as the Supreme Court recently held in this case, HHS and the Departments of Labor and Treasury (“the Agencies”), which collectively administer the ACA, have discretion to create exceptions from that obligation. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2379–82 (2020). The Agencies relied on that discretion, as well as the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb *et seq.*, in promulgating the regulations at issue in this case. J.A. 1–55 (Religious Rule); J.A. 56–95 (Moral Rule) (“the Rules”). The Rules allow employers, based on either their own religious or moral beliefs, to make the Guidelines’ contraceptive coverage requirement inapplicable as to their employees.

Although the Women’s Health Amendment allows the Agencies to create exemptions from the contraceptive care mandate, the Rules here still must be set aside. First, the Rules are arbitrary and capricious in violation of the Administrative Procedure Act’s requirement of reasoned decision making. Second, the Religious Rule creates a religious preference for

employers that allows them to inflict discrete harms upon employees that do not share their religious beliefs, in violation of the Establishment Clause of the First Amendment. Third, the Rules create unreasonable barriers to obtaining medical care. And fourth, the Rules single out women for differential treatment, in violation of the Equal Protection Clause, Section 1557 of the ACA, and Title VII of the Civil Rights Act.

For these reasons, this Court should grant the States' motion, enter summary judgment in their favor, and vacate the Rules.

BACKGROUND

I. Women's Health Guidelines

The Women's Health Amendment to the ACA requires that group health plans and health insurance issuers cover for women, without cost-sharing, "preventive care and screenings . . . as provided for in comprehensive guidelines supported by" HRSA. 42 U.S.C. § 300gg-13(a)(4). After the ACA passed, HRSA commissioned the Institute of Medicine (IOM), a widely respected organization of medical professionals, to recommend what preventive services should be covered for women. *See* J.A. 326–27. The IOM, in turn, convened a committee of sixteen members, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations. *See* J.A. 317–18. After conducting an extensive study, the IOM committee issued a comprehensive report identifying eight evidence-based preventive health services it recommended be covered. J.A. 313–561.

One of the eight preventive services was "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education." J.A. 335. That recommendation was based on evidence that "contraception and contraceptive counseling are effective at reducing unintended pregnancies." J.A. 335. The committee noted that "[n]umerous health professional associations and other organizations recommend the use of

family planning services as part of preventive care for women.” J.A. 335. And the report discussed in detail the health and other risks associated with unintended pregnancies, described studies showing that contraception was effective when used correctly, and explained that cost was a significant barrier to effective use of contraception. J.A. 427–34.

Two weeks after the IOM Committee released its report, HRSA adopted it and issued its first “Women’s Preventive Services Guidelines.” J.A. 310–12. Consistent with the committee’s report, that 2011 version of the Guidelines required health plans to cover “[a] ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” J.A. 311.¹

II. The Agencies Work to Accommodate Religious Objections to Contraception

Shortly after HRSA adopted the IOM report, the Agencies issued an interim final regulation that “provide[d] HRSA with the discretion” to make the Guidelines’ contraceptive coverage requirement inapplicable to any insurance plan maintained by “churches, their integrated auxiliaries, and conventions or associations of churches” and “the exclusively religious activities of any religious order.” *See* J.A. 265; *see also* J.A. 306; 26 U.S.C. § 6033(a)(3)(A)(i) & (iii).

Alongside the exemption for churches and related entities, the Agencies announced, in 2012, that they would further consider how to accommodate organizations that did not qualify for the church exemption but nonetheless objected to providing contraception. Specifically, the Agencies said that they “plan[ned] to develop and propose changes ... that would meet two goals—providing contraceptive coverage without cost-sharing to individuals who want it and

¹ HRSA updated the Guidelines in 2016, 2017, and 2019. J.A. 96–97, 180–82, 312-A. The Guidelines continue to include contraception as a service that is “necessary for women’s health and well-being.” J.A. 312-A.

accommodating non-exempted, non-profit organizations' religious objections to covering contraceptive services." J.A. 300. During this process, the Agencies created a "safe harbor" for certain organizations that did not comply with the Women's Health Amendment's direction to cover the contraceptive methods and services defined in the Guidelines. *Id.*

The Agencies subsequently issued an Advanced Notice of Proposed Rulemaking, a Notice of Proposed Rulemaking, and ultimately a final rule. J.A. 290–97; 269–89; 238–68. The final rule created the "Accommodation," an alternative available to any nonprofit entity that held "itself out as a religious organization" and that had religious objections to "providing coverage for some or all of any contraceptive services required" by the Guidelines. J.A. 243. The Accommodation allowed an employer not to provide contraceptive coverage for its employees if the employer submitted a standardized form to its insurance company (if the employer was fully insured), or third-party administrator (if the employer was self-insured), that informed the insurer or administrator of the religious objection. *See* J.A. 243–44; *see also* 1971–72.

An insurance provider receiving an objection from a fully insured employer was required to "[e]xpressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan," and instead "[p]rovide separate payments for any contraceptive services required to be covered ... for plan participants and beneficiaries for so long as they remain enrolled in the plan." J.A. 265. The insurance provider was further required to "segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services." J.A. 265. Finally, the insurer was required to provide written notice to plan participants and beneficiaries of the fact that "the eligible organization does not administer or fund contraceptive benefits" but that such benefits were available directly from the insurer. J.A. 266.

Under this system, a fully insured, objecting employer could opt out of providing contraception, but their plan participants and beneficiaries would still receive the benefits they were entitled to under the Guidelines. Shifting the burden to the insurer to provide the services directly was not expected to impose additional costs on the insurer, because “[c]overing contraceptives ... yields significant cost savings,” in the form of lower “direct medical costs of pregnancy.” J.A. 241. Thus, as a result of providing contraceptive coverage, the insurance company would expect to see lower expenses from covering other services provided to the organization’s participants and beneficiaries.

Unlike fully insured employers, self-insured employers directly pay for the health expenses they elect to cover, typically with the administrative assistance of an outside organization known as a third-party administrator (TPA). Under the Accommodation, self-insured objecting employers could submit the standardized objection to their TPA. J.A. 263–64. The TPA then assumed the obligation to provide contraceptive coverage to plan participants and beneficiaries, either by paying for contraceptive services directly or by contracting with another entity to do so. J.A. 264. And the TPA was obligated to provide the same notice that insurers were required to provide, stating that the employer did not provide contraceptive benefits, but that such benefits were available from the TPA. J.A. 264.

In these respects, the Accommodation functioned in precisely the same manner for self-insured and fully-insured employers. But because TPAs for self-insured plans do not bear the costs for other benefits provided to plan participants and beneficiaries, they would not be expected to save money by providing contraceptive coverage. As a result, the regulations created a mechanism for HHS to reimburse TPAs for the cost of providing contraceptive coverage, and to offer an allowance for administrative expenses and profit. J.A. 251. The payments operated

through the Federally-Facilitated Exchange user fee that companies participating in federally-administered healthcare exchanges paid. J.A. 251.

III. Litigation over Contraceptive Coverage

Despite the Agencies' efforts, several employers and colleges filed lawsuits challenging their own obligation to cover contraceptive care in existing health plans, or, for those eligible for the Accommodation, to notify their insurer or TPA that they would not be doing so.

In one set of cases, closely held, for-profit corporations that were not eligible for the Accommodation challenged their obligation to cover contraceptive care, arguing that being required to do so violated their rights under the Religious Freedom Restoration Act (RFRA), 42 U.S.C. § 2000bb *et seq.* Two of these challenges were consolidated before the Supreme Court in *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). The Court held in *Hobby Lobby* that requiring closely held, for-profit corporations with religious beliefs that were substantially burdened by covering contraceptive care to do so violates RFRA because the government could promote access to contraceptive care without requiring an objecting employer to cover that care by utilizing the Accommodation mechanism. *Id.* at 728–32.

Three days after its decision in *Hobby Lobby*, the Court ruled that an employer that qualified for the Accommodation could, instead of sending its objection notice to its insurer or TPA, directly notify HHS of its objection. *Wheaton College v. Burwell*, 573 U.S. 958 (2014). The Court stressed, however, that its order should not affect the ability of covered individuals “to obtain, without cost, the full range of FDA approved contraceptives” as HHS could rely on the notice to “facilitate the provision of full contraceptive coverage under the Act.” *Id.*

After these decisions, the Agencies initiated a formal rulemaking process to amend the eligibility criteria for the Accommodation consistent with *Hobby Lobby*, J.A. 218–27, and issued interim final rules to address the Court's order in *Wheaton College*, J.A. 228–37. The interim

rule allowed objecting entities to establish eligibility for the Accommodation by notifying HHS of their objection to covering contraception. J.A. 228–37. Both sets of rules were finalized one year later. J.A. 118–217.

In another set of cases, employers already eligible for the Accommodation alleged that that option violated their rights under RFRA. Many of these cases, including one from the Third Circuit, *see Geneva College v. Dep’t of Health & Human Servs.*, 778 F.3d 422 (3d Cir. 2015), were ultimately consolidated before the Supreme Court in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016). Six days after argument in *Zubik*, the Court directed the parties to submit supplemental briefing to “address whether and how contraceptive coverage may be obtained by petitioners’ employees through petitioners’ insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees.” *Zubik v. Burwell*, 194 L. Ed. 2d 599 (Mar. 29, 2016). The order proposed one such arrangement, but added that “[t]he parties may address other proposals along similar lines.” *Id.* After the parties submitted supplemental briefing, the Court decided that the parties should be “afforded an opportunity to arrive at an approach going forward that accommodates petitioners’ religious exercise while at the same time ensuring that women covered by petitioners’ health plans ‘receive full and equal health coverage, including contraceptive coverage.’” *Zubik*, 136 S. Ct. at 1560. The Court added:

Nothing in this opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by petitioners’ health plans “obtain, without cost, the full range of FDA approved contraceptives.”

Id. at 1560–61 (citations omitted). The Court vacated all lower court decisions in the consolidated cases. *Id.* at 1560.

Several months after the Court’s order in *Zubik*, the Agencies announced that “no feasible approach has been identified . . . that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage,” J.A. 172. Because the Accommodation best reconciled access to contraceptive coverage and religious objections to providing that coverage, the Agencies left that process in place. J.A. 172–73. Several more months later, the Third Circuit again ruled that the Accommodation does not violate RFRA. *Real Alternatives, Inc. v. Dep’t of Health & Human Servs.* 867 F.3d 338, 359–66 (3d Cir. 2017).

IV. The Agencies’ Rules

In May 2017, President Donald Trump issued an Executive Order directing the Agencies to “consider issuing amended regulations” to address “conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of Title 42, United States Code.” J.A. 167–168. The order did not acknowledge the Court’s instruction in *Zubik* that the Agencies ensure that women covered by health plans offered by objecting entities “receive full and equal health coverage, including contraceptive coverage.” 136 S. Ct. at 1560 (citation omitted). Later that year, the Agencies issued two interim final rules—one addressing religious objections to contraception and one to moral objection to contraception—which became effective a week before they were published in the Federal Register. J.A. 98 – 141 (interim Religious Rule); J.A. 141 – 166 (interim Moral Rule). The two interim rules made several sweeping changes to the availability of contraceptive coverage.

Over the next year, the Agencies accepted comments on the interim rules. Then, in November 2018, the Agencies issued final versions of the Rules, which maintained the substantive changes first promulgated through the interim versions. J.A. 1–55; 56–95. Among those changes, the Rules:

Create a Greatly Expanded Religious Exemption for Employers: The Religious Rule directs that an employer may make the Guidelines’ contraceptive coverage requirement inapplicable to its employees if the employer has a religious objection to covering or arranging payments for contraceptive care, or objects to having an insurer or TPA do so. 45 C.F.R. § 147.132(a); *see also* J.A. 55. According to the Agencies, a complete exemption of this sort is needed because the Accommodation itself violates RFRA in many cases. J.A. 11–12.

Other than for churches and affiliated entities, the Agencies have never before directed that certain health insurance plans be altogether removed from the otherwise general requirement to cover contraceptive care without cost sharing. The consequence for any woman covered by such a plan is the loss of coverage, without cost sharing, for contraceptive services and counseling. The Religious Rule does not create any mechanism for women who will lose coverage to obtain it from other sources, and it does not suggest that the Agencies will work to ensure that any such women have coverage.

Create a Moral Exemption for Employers: The Agencies also created a moral exemption that functions much like the religious exemption. 45 C.F.R. § 147.133(a); *see also* J.A. 94–95. The Moral Rule does not define what beliefs qualify as a “sincerely held moral conviction” sufficient to claim the exemption. Not only have the Agencies never before created a moral exemption, the Agencies have never before permitted a moral objector to use the Accommodation.

Create an Individual Exemption: The Rules also create, for the first time, a process for individuals to make the Guidelines’ contraceptive coverage requirement optional as to the insured’s plan, if the insured has a religious or moral objection to contraception. 45 C.F.R. §§ 147.132(b), 147.133(b); *see also* J.A. 55, 95.

Make the Accommodation Optional: The Rules make the Accommodation optional in all cases. 45 C.F.R. § 147.131; *see also* J.A. 54. As a result, no objecting employer is required to use it, even if the Accommodation would fully satisfy any religious or moral objection to covering contraceptive care.

Allow Publicly Traded Corporations to Use Exemption or Accommodation: The Religious Rule, but not the Moral Rule, makes the newly created exemption available to publicly traded corporations. 45 C.F.R. § 147.132(a)(1)(i)(D); *see also* J.A. 55 The Agencies justify this expansion by claiming “in a country as large as America comprised of a supermajority of religious people, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.” J.A. 27.

Fail to Require Notice: The Rules provide that “exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them.” J.A. 23; *accord* J.A. 78. Rather, the only notice that exempted plans are required to provide participants is that which ERISA already mandates. So long as plans that do not provide contraception indicate that fact somewhere in their plan documents, they fully comply with the Rules. J.A. 23, 78–79.

V. This Action

Pennsylvania filed this action shortly after the agencies issued the interim rules. *See* Compl., ECF No. 1. The complaint alleged that the Rules are contrary to the Constitution’s guarantee of equal protection, to Title VII of the Civil Rights Act, the Pregnancy Discrimination Act, and to the Establishment Clause, and violated both the APA’s substantive and procedural limitations on agency rulemaking. *Id.* ¶¶ 141–76. Pennsylvania moved for a nationwide

preliminary injunction, *see* Mot. Prelim. Inj., ECF No. 9, which this Court granted in December 2017, *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017). The Court concluded that the agencies had improperly failed to take comment before issuing the interim rules, in violation of the procedural requirements of the APA, and that the agencies lacked statutory authority under the ACA to create exemptions from the requirements of the Women’s Health Amendment, and that those exemptions could not be separately justified by RFRA. *Id.* at 570–81.

While the first preliminary injunction was on appeal, the agencies finalized the Rules. Pennsylvania—joined by New Jersey—filed an amended complaint challenging the final versions of the Rules on the same grounds as the interim versions. *See* Am. Compl., ECF No. 89. Three days later, the States filed a second motion for a preliminary injunction. *See* Mot. Prelim. Inj., ECF No. 90. This Court again entered a nationwide preliminary injunction. *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019). The Court concluded that the Agencies’ acceptance of comments following the issuance of the interim rules did not cure their violation of the APA’s procedural requirements, and that the agencies lacked authority, under either the Women’s Health Amendment or RFRA, to create exemptions from the Guidelines, *id.* at 812–27.

On appeal, the Third Circuit affirmed this Court’s decision in all respects. *Pennsylvania v. President*, 930 F.3d 543 (3d Cir. 2019). That court agreed that the procedure followed by the agencies was defective, as the agencies had not allowed for the opportunity to comment on a proposal. *Id.* at 565–69. And that court further held that the Women’s Health Amendment did not give the agencies the discretion to create exemptions from the Guidelines, and that RFRA neither required nor authorized the Religious Rule independent of the Women’s Health Amendment. *Id.* at 570–74. Finally, it upheld the scope of the nationwide injunction entered by this Court. *Id.* at 575–76.

The Supreme Court reversed the court of appeals. The Court first held the Women’s Health Amendment provides the Agencies with discretion to define both what services must be covered, and who must cover them. *Little Sisters*, 140 S. Ct. at 2380 (citations omitted). The Court then briefly discussed RFRA, rejecting the argument “that the Departments could not even consider RFRA as they formulated the religious exemption from the contraceptive mandate.” *Id.* at 2382–83.² The Court made clear, however, that it “need not reach” whether RFRA required or authorized the Rules. *Id.* at 2382. The Court next held that the Agencies’ acceptance of comments following the issuance of the interim rules satisfied the requirements of the APA, effectively overruling the Third Circuit’s decision in *NRDC v. EPA*, 683 F.2d 752 (3d Cir. 1982), as well as similar decisions from other courts of appeals.

Justices Alito and Gorsuch concurred with the majority’s opinion, but also would have ruled that RFRA compelled the Religious Rule. Justice Alito wrote that “RFRA compels an exemption for the Little Sisters and any other employer with a similar objection to what has been called the accommodation to the contraceptive mandate.” *Little Sisters*, 140 S. Ct. at 2387 (Alito, J., concurring).

Justice Kagan, joined by Justice Breyer, concurred in the judgment only. Justice Kagan concluded that the language of the Women’s Health Amendment was ambiguous and that the Agencies’ interpretation was entitled to *Chevron* deference. *Id.* at 2397 (Kagan, J., concurring). Justice Kagan stressed, however, that the Court’s conclusion on the scope of the Women’s Health Amendment “does not mean the Departments should prevail when these cases return to the lower courts.” *Id.* Rather, Justice Kagan stressed that “[a]n agency acting within its sphere of

² Although the Court characterized this as “respondents’ argument,” the States had, in fact, argued to the contrary. *See, e.g.*, Transcript of Oral Argument at 79:13–15, *Little Sisters of the Poor Saints Peter and Paul Home*, 140 S. Ct. 2367 (2020) (Nos. 19-431 & 19-454) (“We don’t dispute that agencies should take RFRA into account.”).

delegated authority can of course flunk the test of ‘reasoned decisionmaking.’” *Id.* at 2398 (Kagan, J., concurring). Justice Kagan then described several ways in which the agencies had probably done so here, ranging from the decision to “exempt[] all employers with objections to the mandate, even if the accommodation met their religious needs” to the inclusion of publicly traded companies within the scope of the Religious Rule, to the issuance of the Moral Rule altogether, which could not be justified by RFRA. *Id.* at 2398–2400.

Justice Ginsburg, joined by Justice Sotomayor, dissented. Justice Ginsburg criticized the majority for “cast[ing] totally aside countervailing rights and interests in its zeal to secure religious rights to the nth degree.” *Id.* at 2400 (Ginsburg, J., dissenting). Justice Ginsburg read the Women’s Health Amendment to grant HRSA the authority to identify *what* preventive services were to be covered, but not *who* was to cover them. *Id.* at 2404–06. Justice Ginsburg then rejected the government’s alternative argument that RFRA justified the Religious Rule, noting that the Rule “imposes significant burdens on women employees” and that the Accommodation “does not substantially burden objectors’ religious exercise.” *Id.* at 2407–11.

ARGUMENT

Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). In a challenge brought under the APA, the Court must hold unlawful and set aside any agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” that is “contrary to constitutional right,” or that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A)–(C).

The Rules fail on all accounts. First, the Rules do not comply with the APA’s demand of reasoned decision making (Count IV). Second, the Religious Rule violates the Establishment

Clause (Count V). Third, the Rules erect an unreasonable barrier to appropriate medical care, in violation of Section 1554 of the ACA. (Count IV). Fourth, the Rules' unequal treatment of women violates the Equal Protection Clause, Section 1557 of the ACA, and Title VII of the Civil Rights Act of 1964 (Counts I, II & IV). Thus, the Rules must be vacated.

I. The Rules Are Arbitrary and Capricious

Agency action must be set aside if the agency failed to “examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (cleaned up). Agency action also must be vacated if the agency “entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Id.* And in conducting this review, “an agency’s action must be upheld, if at all, on the basis articulated by the agency itself.” *Id.* at 50. And anytime agency action constitutes a change to existing policy, the agency must provide a “reasoned explanation” and “show that there are good reasons for the new policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

A. The Religious Rule Does Not Reasonably Address the Problem it Purports to Resolve

The Religious Rule’s purpose is to “expand the protections for the sincerely held religious objections of certain entities and individuals.” J.A. 2. As the Supreme Court has now held, the Agencies’ discretion under the Women’s Health Amendment permits them to protect religious objections to contraception because “the potential for conflict between the contraceptive mandate and RFRA is well settled.” *Little Sisters*, 140 S. Ct. at 2383. Still, the APA demands a “rational connection” between any conflicts that exist and the Agencies’ chosen

solution. *State Farm*, 463 U.S. at 43; *see also Little Sisters*, 140 S. Ct. at 2398 (Kagan, J., concurring). So here, the solution—i.e., the Religious Rule—must reasonably target whatever conflicts exist between either the requirement that group health plans cover contraceptive care or the Accommodation and RFRA. “Assessed against that standard of reasonableness, the exemptions HRSA and the Departments issued give every appearance of coming up short.” *Little Sisters*, 140 S. Ct. at 2398 (Kagan, J, concurring).

First, a RFRA violation exists only when the government “substantially burden[s]” the exercise of religion. 42 U.S.C. § 2000bb-1(a). The Religious Rule, however, makes the Guidelines’ inclusion of contraceptive coverage inapplicable to any employer that merely *objects* to contraception based on a sincerely held belief. 45 C.F.R. § 147.132(a)(2). The objecting employer need not even claim that directly covering contraception, or complying with the Accommodation, would cause a substantial burden.

Second, the Religious Rule allows an employer for which the Accommodation would fully resolve any conflict with RFRA to still make the Guidelines’ contraceptive coverage requirement inapplicable to that employer’s employees.³ Conflicts with RFRA cannot justify empowering employers to erase the Guidelines’ contraceptive coverage requirement when, under the existing options, there was no RFRA conflict to begin with. And in the Religious Rule, the Agencies concede that some employers for whom the Accommodation relieves any RFRA violation may elect to use the exemption. J.A. 26, 41–42. This over inclusiveness is problematic because only the Accommodation preserves access to contraceptive coverage, and contraceptive methods and counseling are among the Guidelines’ list of services that are “necessary for women’s health and well-being”—a conclusion that the Rules do not disturb. *See supra*

³ The Moral Rule shares this flaw, as the Accommodation process is just an optional alternative to an exemption. J.A. 87.

Background Parts II & IV; J.A. 8, 68, 312-A. By the Agencies’ own commitments, then, a reasonable solution to any RFRA violation would do as little damage as possible to women’s access to contraception. But the Agencies have not been guided by that priority. Instead, they have extended the exemption even when it is not needed to serve the Rules’ purported objectives. And in every instance in which the Accommodation fully resolves an entity’s religious or moral objection, but the entity elects the exemption instead, the Rules “yield[] all costs and no benefits,” *Little Sisters*, 140 S. Ct. at 2399 (Kagan, J., concurring).

Third, the Religious Rule improperly covers publicly traded corporations, despite the Supreme Court having never held that RFRA covers those corporations. Even if RFRA does cover publicly traded corporations, the Agencies’ explanation for their novel interpretation is too thin to justify the expansion. The Agencies arrive at their conclusion because, under RFRA, the government may not “substantially burden a person’s exercise of religion,” and under 1 U.S.C. § 1 “person” includes corporations. J.A. 27. Yet when the Court extended RFRA’s protections to closely-held corporations, section 1 was just a part of the Court’s analysis. *See Hobby Lobby*, 573 U.S. 707–09. Before the Court turned to section 1, the Court also considered the purpose of RFRA and the consequences of an alternate conclusion. *Id.* at 705–07. If section 1 were enough reason to extend RFRA to closely-held corporations, the first half of the Court’s reasoning in *Hobby Lobby* on this point would be superfluous. Nevertheless, the Agencies consider section 1 enough to extend RFRA even further than the Court did in *Hobby Lobby*.

Compounding this third problem, when the Court extended RFRA to closely held for-profit corporations, it dismissed concerns about whether a corporation can form a religious belief. The Court did, however, distinguish the foreign idea of “unrelated shareholders” running a corporation under a shared set of religious beliefs from closely-held corporations doing so. *Id.*

at 717. At one point in the Religious Rule, the Agencies quote language from *Hobby Lobby* noting the peculiarity of publicly-traded companies coalescing around a shared religious tenet. J.A. 44–45. Nevertheless, elsewhere in the Religious Rule, the Agencies still claim that “the mechanisms for determining whether a [publicly traded] company has adopted and holds certain principles or views, such as sincerely held religious beliefs, [] a matter of well-established State law with respect to corporate decision-making.” J.A. 27. While some facets of corporate decision making may be well settled, the discomfort that the Supreme Court displayed toward publicly traded corporations expressing a religious belief for purposes of RFRA shows that how—or even whether—a publicly traded may do so is far from settled. Thus, on this point, too, the Agencies have not reasonably justified that including publicly-traded corporations within the Religious Rule remedies any actual RFRA violations.

Finally, the Religious Rule allows employers to claim the exemption without providing any notice of that decision to the government, insurer, or TPA. J.A. 23.⁴ Without a notice requirement, or something similar, the Religious Rule lacks any mechanism for the sincerity of an employer’s religious belief to be evaluated. And the Religious Rule omits such a mechanism even though an essential part of the Court’s decision to extend RFRA to closely held corporations was that insincere claims of a substantial burden on religion could be distinguished from sincere ones. *Hobby Lobby*, 573 U.S. at 717–18. Because courts can distinguish the two, the Supreme Court discounted concerns that for-profit entities would take advantage of RFRA, noting that “[t]o qualify for RFRA’s protection, an asserted belief must be ‘sincere’; a corporation’s pretextual assertion of a religious belief in order to obtain an exemption for financial reasons would fail.” *Hobby Lobby*, 573 U.S. at 717 n.28. Under the Religious Rule,

⁴ The same is true of the Moral Rule. J.A. 78–79.

however, honest and pretextual beliefs, which in either case need not even be substantially burdened, qualify for the exception all the same. In *Hobby Lobby*, the Court criticized a failed bill that also lacked any mechanism for scrutinizing an objector's belief for "extend[ing] more broadly than the pre-existing protections of RFRA," *id.* at 719 n.30, a part of *Hobby Lobby* the Religious Rule fails to acknowledge.

In each of these ways, the Religious Rule is not a reasonable resolution of any conflicts that exist between the Guidelines' contraceptive coverage requirement and RFRA.

B. The Agencies Did Not Reasonably Conclude that the Religious Rule Resolves Any RFRA Violations

The Religious Rule suffers an additional flaw: the Agencies have not reasonably determined that rule is needed to remedy any RFRA violations. Indeed, according to precedent still binding on this Court, the Accommodation does not impose a substantial burden, and so does not violate RFRA. *Real Alternatives*, 867 F.3d at 359–66; *see also Pennsylvania*, 930 F.3d at 573 & n.30, *rev'd and remanded on other grounds*.

No Supreme Court ruling upsets *Real Alternatives*' weight in this Court. *Zubik* precedes *Real Alternatives*, and so does not warrant disregarding *Real Alternatives*. And *Little Sisters* is not inconsistent with *Real Alternatives*. There, the Supreme Court repeated that, for purposes of RFRA, courts must accept the "sincerely held complicity-based objections of religious entities." *Little Sisters*, 140 S. Ct. at 2383. But the Court did not say that courts must passively accept any claim that a religious entity is substantially burdened by the operation of a generally applicable rule, or that courts must accept that a burden exists when the claimed burden is premised on a faulty characterization of law. *See Real Alternatives*, 867 F.3d at 356 (rejecting these positions). Nor did the Court say that the Accommodation imposes a substantial burden, or that it ever held as much in *Zubik*. *Little Sisters*, 140 S. Ct. at 2383. Instead, the Court said only that it was

appropriate for the Agencies, when revisiting the contraceptive coverage guarantee after *Zubik*, to consider what RFRA required. *Id.*

And, in the Religious Rule, the Agencies' evaluation of whether the Accommodation is substantially burdensome fails to acknowledge the Third Circuit's majority opinion in *Real Alternatives*; rather, the only mention of the case is a citation to the dissent. J.A. 24 n.56. Ignoring *Real Alternatives* while extending RFRA into new territory is all the more remarkable because *Real Alternatives* was one of only two published decisions by a court of appeals addressing a RFRA challenge to the contraceptive mandate following the remand in *Zubik* and prior to the issuance of the interim rules. *See Ozinga v. Price*, 855 F.3d 730, 736 (7th Cir. 2017) (dismissing challenge to mandate as moot in light of *Hobby Lobby*). RFRA, of course, is not a statute that any of the Agencies administers. Rather, conclusively resolving what RFRA requires is the job of the courts. Concluding that the Accommodation may substantially burden religious beliefs without addressing key judicial decisions constitutes unreasoned decision making. Exacerbating this error, the only decision other than *Hobby Lobby* that the Agencies cite to support that the Accommodation imposes a substantial burden is a decision of the Eighth Circuit. But the Agencies avoid that that decision was vacated by the Supreme Court following *Zubik*. *See* J.A. 11; *see also U.S. Dep't of Health & Human Servs. v. CNS Ministries*, No. 15-775, 2016 WL 2842448, at *1 (May 16, 2016) (vacating *Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs.*, 801 F.3d 927 (8th Cir. 2015)).

Even if the Accommodation substantially burdened religious exercise, the Agencies would need to have reasonably considered the governmental interests at stake and whether the Accommodation was the least restrictive means of accomplishing those interests before they concluded that the Accommodation violates RFRA. 42 U.S.C. § 2000bb-1(b). But the Agencies

do not seriously grapple with either. For the reasons discussed in the following section, the Agencies’ contention that there is no compelling interest at stake is both deficient on its own, and an inadequately justified change of position. Moreover, the Agencies do not separately consider whether the Accommodation is in fact the least restrictive method of facilitating access to contraception.⁵

Because the Agencies did not reasonably conclude that the Accommodation substantially burdens religious beliefs, the Agencies did not reasonably conclude the Accommodation implicates RFRA. And because the Agencies’ conclusion on this point is unsupported, the justification for promulgating a rule to remedy RFRA violations crumbles. Even if the Accommodation can impose a substantial burden, the Agencies did not justify their new view that the Accommodation is not the least restrictive way of furthering a compelling government interest. For any of these reasons, the Religious Rule is arbitrary and capricious.

C. The Agencies Failed to Provide a Reasoned Explanation for Their Reversal on the Safety, Efficacy, and Benefits of Contraception

In part, the Agencies conclude that the Religious Rule was a reasonably way to resolve conflicts with RFRA because of doubts about the safety, efficacy, and benefits of contraceptive care, which in turn undermine any compelling interest in facilitating access to that care. J.A. 13. Independently, each rule relies on the Agencies’ doubts about the health benefits of

⁵ The Religious Rule mentions Title X clinics as one alternative that would allow women who lose coverage for contraceptive care because of the rule to receive contraceptive care even without insurance coverage. According to the Agencies, HHS’s then-pending rule relating to Title X “would amend the definition of ‘low income family’—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers’ religious beliefs or moral convictions.” J.A. 16. But in the final Title X rule, HHS said that those who believed the rule “requires project directors to consider women as being from a low income family if they have this insurance status” were under a “mistaken impression.” J.A. 2592. Therefore, women who lose coverage because of the Religious Rule cannot be assured of receiving contraceptive care through a Title X clinic.

contraception. J.A. 17–21, 73–77. Those doubts constitute a changed position for the Agencies, which until 2017 had consistently promulgated rules about covering contraceptive methods and counseling that recognized those services are safe, effective, and beneficial. *See* J.A. 173, 241–42, 256, 300–01. Indeed, the FDA, another component of HHS, has approved 18 different methods of contraception as safe and effective. J.A. 2344–67. And in prior rules, the Agencies had adopted the IOM’s conclusions that contraception promotes healthier outcomes for mothers and children. *See* J.A. 241, 256, 300.

Agencies may “change their existing policies,” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016), but must provide a “reasoned explanation” and “show that there are good reasons for the new policy.” *Fox Television*, 556 U.S. at 515. And when an agency’s “new policy rests upon factual findings that contradict those which underlay its prior policy” and “its prior policy has engendered serious reliance interests,” the agency must provide “a more detailed justification.” *Id.* Here, the Rules lack a detailed—or even reasoned—explanation for the Agencies’ changed stance on the safety, efficacy, and benefits of contraceptive care.

Before 2017, the Agencies had determined that because women face unique health needs associated with the ability to become pregnant, and because unintended pregnancy poses health risks, contraception is a preventive service. J.A. 241, 256, 300. And because cost sharing is a barrier to effective contraception use, the Agencies also concluded that the contraceptive care requirement is necessary to remedy a critical gender disparity that prevents women from achieving equal health outcomes with men. *Id.* Those findings generated significant reliance interests: the Agencies acknowledge in the Religious Rule that between 55.6 million and 62.4 million women covered by private insurance currently have cost-free contraceptive coverage, J.A. 43, and concede that at least 70,515 women will lose coverage under the Rules, J.A. 43, 91.

In the final Rules, the Agencies backtrack. J.A. 17–21, 73–77. Faced with some comments asserting that contraception poses health risks to women, that some forms of contraception are actually abortion, and that contraception has not reduced teen pregnancy, the Agencies decline to “take a position on the[se] empirical question[s].” J.A. 20; *accord* J.A. 75.⁶ They likewise conclude that “it is not clear” that the Rules “will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate”—even though the Rules permit employers to dictate whether employees who want to use contraceptive care and services can enroll in insurance plans that cover those services without cost sharing. J.A. 20–21; *accord* 76–77.⁷

The Agencies have not justified reversing course. In fact, their conclusions “run[] counter to the evidence before the agency.” *State Farm*, 463 U.S. at 43. First, the Agencies identify some “empirical questions”—including how severe the side effects of contraceptive methods are and whether contraception increases or decreases unintended pregnancies—that indicate that “significantly more uncertainty and ambiguity exists on these issues.” J.A. 20; *see also* J.A. 75. But the suggestion of uncertainty, as to both side effects and efficacy, irrationally treats all 18 forms of FDA-approved contraception as indistinguishable. No one method of contraception is right for everyone, and that one method might produce ill effects in one person does not mean that all 17 other approved methods will. This is exactly why the Agencies had previously

⁶ Only some of the 27 total comments supporting the Rules raised these concerns with any specificity. *See* J.A. 1529–48, 1552–66, 1570–86.

⁷ The Agencies had previously explained that the church exemption would likely not negatively impact women because houses of worship “are more likely than other employers to employ people of the same faith who share the same objection.” J.A. 243. But the Agencies had rejected expanding the exemption to other employers precisely because female employees of non-religious employers are “less likely than individuals in plans of religious employers to share their employer’s (or institution of higher education’s) faith and objection to contraceptive coverage on religious grounds.” J.A. 256. The Agencies have not abandoned that position.

concluded that “[i]t is for a woman and her health care provider in each particular case to weigh any risks against the benefits in deciding whether to use contraceptive services in general or any particular contraceptive service.” J.A. 242; *see also* J.A. 2344 (“No one product is best for everyone. Some methods are more effective than others at preventing pregnancy.”). Moreover, the Rules avoid that all medication has side effects and can be contraindicated for some patients.

Nor do the Agencies point to new evidence that all 18 forms of FDA-approved contraception are *categorically* unsafe for women, or to any evidence contradicting their prior conclusion that unintended pregnancy is a health risk for women. Beyond that, the Agencies ignore the FDA’s undisputed determination that the 18 approved methods of contraception are “proven safe and effective,” J.A. 2364–67, even though all methods of contraception, like all medical services, must be individually prescribed, J.A. 2344 (“No one product is best for everyone. . . . This page lists FDA-approved and cleared methods for birth control. Talk to your healthcare provider about the best method for you.”). And the Agencies ignore the overwhelming consensus of the medical community in support of contraception’s safety and efficacy. *E.g.* J.A. 628, 631–32, 641, 643, 647–48, 650–51, 659, 1662–76, 1667–84, 1685–1705, 1784–92. The Rules, then, concoct a scientific controversy to newly discover “uncertainty and ambiguity” about the safety, efficacy, and benefits of contraceptive care. J.A. 20.

To reject the scientific consensus, the Agencies point to comments that certain forms of contraception are “abortifacients.” J.A. 19, 74. While the Agencies recognized the religious tenor of these comments, *id.*, they still made commenters’ religious views part of the rationale for reversing course on the health effects of contraception and how certain forms of contraception prevent pregnancy. *See* J.A. 257 (“FDA-approved contraceptive methods, including Plan B, Ella, and IUDs, are not abortifacients within the meaning of federal law.”). Personal religious beliefs

about how a form of medicine operates may matter for RFRA, but not for the health effects of contraception. So relying on those comments to support scientific conclusions, as the Agencies did, was unreasonable.

The Agencies' new position is contrary not just to science and positions in previous rules, but also contrary to HHS's current definition of pregnancy. *See* 45 C.F.R. § 46.202(f) (defining pregnancy as "the period of time from implantation until delivery"). HHS's current definition of pregnancy comports with that of the medical community. J.A. 712 (noting that since 1965, the American Congress of Obstetricians and Gynecologists (ACOG) has recognized that "the establishment of a pregnancy takes several days and is not completed until a fertilized ovum is implanted in the lining of the woman's uterus." (citations omitted)). As ACOG and many other commenters stated, "[e]very FDA-approved contraceptive method acts before implantation, does not interfere with an existing pregnancy, and is not effective after a fertilized egg has implanted successfully in the uterus." J.A. 647 (citations omitted); *see also, e.g.*, 62 Fed. Reg. 8610, 8611 (Feb. 25, 1997) (FDA's conclusion that "[e]mergency contraceptive pills are not effective if the woman is pregnant" and have no "adverse effect on the fetus" if taken when a woman is pregnant). The Agencies have presented no scientific evidence to support a redefinition of pregnancy, rendering this analysis arbitrary and capricious.⁸

In addition, the Agencies decline to "take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy," but still use purported ambiguity over this empirical question to conclude that "it is difficult to establish causation between

⁸ The Agencies also misrepresent how the FDA itself describes several methods of contraception. J.A. 19 n.39, 74 n.41. The FDA notes that several forms of contraception "may also work . . . by preventing attachment (implantation) to the womb (uterus)." J.A. 2363. The Agencies insert the words "of a human embryo after fertilization," which the FDA did not use. *See id.*

granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general.” J.A. 19; *accord* J.A. 75. For HHS, that position disregards an earlier conclusion that the 63% decline in teen pregnancy between 1990 and 2013 “is due to the combination of an increased percentage of adolescents who are waiting to have sexual intercourse and the increased use of effective contraceptives by teens.” J.A. 2556–63. The studies cited by the Agencies do not suggest otherwise: that other factors have influenced the undisputed decline in teen pregnancy does not eliminate the role of increased access to contraception, and that many women who had abortions were using contraception when they got pregnant only highlights the problem of women inconsistently using less effective methods. *Cf.* J.A. 19–20, 75. Here, too, there is no evidence suggesting any “uncertainty and ambiguity” over the effectiveness of contraception.

Finally, the Agencies summarily conclude that the Rules “are not likely to have negative effects on the health or equality of women nationwide,” after again declining to take a position on “those evidentiary issues.” J.A. 21, 76–77. But the Agencies fail to provide any evidence contradicting their earlier conclusions that contraception “improves the social and economic status of women” and that contraceptive coverage without cost sharing is necessary to eliminate the “financial barriers that prevented women from achieving health outcomes on an equal basis with men.” J.A. 241, 256, 300. Additionally, the Agencies provide no source supporting any ambiguity over the impact of contraception or the mandate on unintended pregnancy, and their only source for claiming that state mandates “have not necessarily lowered rates of unintended pregnancy (or abortion) overall” is a law review article, not a research study. J.A. 20 & n.53, 76 & n.56. The Agencies ignore several comments proving that Colorado’s contraceptive mandate, for example, reduced the unintended pregnancy and abortion rate, J.A. 799–800, 807,

1330—claiming instead that no commenter provided empirical data about state contraceptive equality mandates, J.A. 20, 76. The Agencies also ignore comments showing that the contraceptive coverage requirement has allowed women to choose longer-term and more effective forms of contraception, which decreases the risk of unintended pregnancies. *E.g.*, J.A. 1033, 1125, 1151–52, 1329–30.

At bottom, the Agencies have failed to provide a reasoned explanation—much less a detailed justification—for their newfound view that contraception is not safe, effective, and beneficial for women. *See Fox Television*, 556 U.S. at 515. And all evidence cuts against the Agencies’ conclusion. For these reasons, the Rules are arbitrary and capricious.

D. The Agencies Provided No Reasoned Justification for the Moral Rule

The Moral Rule has even more defects. To begin, it is the product of the Agencies having “relied on factors which Congress has not intended [them] to consider.” *State Farm*, 463 U.S. at 43. Given the history of challenges to the contraceptive guarantee under RFRA, it was proper for the Agencies to look to potential conflicts with RFRA to inform the exercise discretion that exists under the Women’s Health Amendment. *Little Sisters*, 140 S. Ct. at 2383. But there is no history of litigation for moral objections like the history of litigation that has transpired under RFRA. Nor does anything in the ACA direct the Agencies to consider moral objections to any covered health service during the exercise of their discretion under the Women’s Health Amendment.

Without a statute like RFRA or any sign in the ACA that the Agencies should consider moral objections, the Agencies instead justify the Moral Rule by invoking unrelated instances of Congress respecting morally-informed objections to generally applicable laws. J.A. 62–64. Of course, the ordinary inference to draw from Congress having created moral exceptions to other generally applicable laws, but not to the ACA, would be that the difference is intentional. *See*,

e.g., Loughrin v. United States, 573 U.S. 351, 358 (2014) (explaining Congress’s use of language in one section of a statute, but not another, ordinary is intentional); *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 384 (2013) (applying same interpretive principles across statutes). Each reason the Agencies supply for departing from that standard inference is unsound.

The Agencies first explain that inferring anything from Congress’s failure to include a moral exception in the ACA would prove too much because it would “negate not just [the moral] exemptions, but the previous exemptions provided for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation.” J.A. 63. That conclusion is wrong. Congress’ omission of religious exemptions from the ACA is irrelevant because RFRA applies to all federal statutes and regulations. Congress would have needed to explicitly exempt the ACA from RFRA’s reach to make substantial burdens on religion an improper factor to consider. *Little Sisters*, 140 S. Ct. at 2383. But RFRA does not apply to moral beliefs. So, unlike religious beliefs, Congress needed to have affirmatively made moral beliefs a factor for the Agencies to properly consider them, but did not.

Additionally, the Agencies deem the Moral Rule a reasonable exercise of discretion because of their history of using the discretion afforded under the Women’s Health Amendment for religious exemptions. *See* J.A. 61. Yet the existence of RFRA makes the impetus for accommodating religious interests distinct. *Little Sisters*, 140 S. Ct. at 2382–84. So the Agencies’ past practice of accommodating substantial burdens on religion has no bearing on whether the Agencies should accommodate moral beliefs.

Next, the Agencies note that while Congress did not include conscience-based exemptions from the Women’s Health Amendment, Congress also did not require that that Agencies cover contraception. J.A. 67. From there, the Agencies hypothesize that had Congress

known the Women’s Health Amendment would encompass contraception, then Congress would have included a conscience exemption too. *Id.* Yet the Agencies’ inferences about congressional intent fail to address evidence suggesting that each conclusion—that Congress would have been surprised HRSA’s Guidelines include contraception and that, if Congress had known contraception would be covered, it would have included exemptions—is wrong. The legislative record for the Women’s Health Amendment is replete with evidence that Congress expected contraception would be covered. *See, e.g.*, 155 Cong. Rec. 28,841 (2009) (Sen. Boxer); *id.* at 28,843 (Sen. Gillibrand); *id.* at 28,844 (Sen. Mikulski); *id.* at 29,070 (Sen. Feinstein); *id.* at 29,311 (Sen. Nelson). And after the first version of the Guidelines, which included contraception, was released, Congress voted against adding conscience exemptions that functioned just as the Moral Rule does. 158 Cong. Rec. 2621–34 (2012); *see also Hobby Lobby*, 573 U.S. at 719 n.30 (describing this legislative history). The best, then, that can be said about the Agencies’ analysis of legislative intent is that it ignores important evidence. More accurately, however, that analysis is contrary to the available evidence.

Finally, the Agencies note that other federal agencies and States have allowed for exceptions to neutral laws based on moral objections. J.A. 65. The Agencies likewise comment on founding-era respect for conscientious objections. J.A. 66. Whether the Agencies’ account of those sources is accurate, it is beside the point. Any discretionary agency action must be based on the specific factors Congress has made relevant to that action. *State Farm*, 463 U.S. at 43.

For any of these reasons, the Moral Rule is the product of unreasonable decision making.

E. The Agencies Failed to Consider Significant Comments

No matter the substance of an agency’s rule, an agency may not have arrived at its conclusions having “failed to consider an important aspect of the problem.” *State Farm*, 463 U.S. at 43. That means an agency must “respond in a reasoned manner to those [comments] that raise

significant problems. *City of Waukesha v. EPA*, 320 F.3d 228, 257 (D.C. Cir. 2003)); *see also* *United States v. Nova Scotia Food Prod. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977). These responses “enable the Court to see what major issues of policy were ventilated and why the agency reacted to them as it did.” *Am. Coll. of Emergency Physicians v. Price*, 264 F. Supp. 3d 89 (D.D.C. 2017). “[F]ailure to address these comments, or at best its attempt to address them in a conclusory manner, is fatal to its defense.” *Ass’n of Private Sector Colleges & Universities v. Duncan*, 681 F.3d 427, 449 (D.C. Cir. 2012) (cleaned up).

Of the 110,000 comments recognized by the Agencies, only 27 comments (representing 17 unique individuals or organizations) supported the religious and moral exemptions. J.A. 5, 60 (providing number of comments); *see also* J.A. 1502–93 (collecting all unique comments supporting the Rules). Put differently, only 0.025% of comments supported the Rules; 99.96% opposed them. Yet the Agencies nowhere acknowledge this significant disparity, nor do they modify the exemptions in any way to increase contraceptive coverage for women. Instead, the Agencies treat these 27 comments as bearing equivalent weight to the more than 109,950 comments opposing the Rules.

The Agencies ignored several other comments of significance:

- The American medical community—including the American Academy of Family Physicians (J.A. 628–629), the American Academy of Nursing (J.A. 630–39), the American College of Nurse-Midwives (J.A. 640–42), the American College of Physicians (J.A. 643–45), the ACOG, the American Academy of Pediatrics, the Society for Adolescent Health and Medicine (J.A. 646–55), and the American Public Health Association (J.A. 656–62)—unequivocally opposed the Rules as anti-science and harmful to women. But the Agencies nowhere acknowledge the elevated importance of comments by medical professionals in Rules impacting the medical needs of women.
- Many commenters explained that other state- and federal-funded programs cannot meet an increased need for contraceptive coverage. *E.g.*, J.A. 600–02, 634–37, 653, 660–61, 1065–66, 1184–86, 1337–39, 1355–56, 1463–65. In particular, commenters stated that Title X is insufficiently funded to meet existing needs, much less absorb an increase from women who lose access due to objecting employers. *E.g.*, J.A. 600–02, 634–37, 653,

660–61, 1065–66, 1184–86, 1337–39, 1355–56, 1463–65. But the Agencies ignored these concerns, insisting only that then-proposed changes to Title X “could further reduce any potential effect of these final rules on women’s access to contraceptives.” J.A. 16.⁹

- The contraceptive mandate required coverage not just for contraceptive methods but for contraceptive counseling. A number of commenters noted the specific importance of contraceptive counseling, “during which an individual could discuss her specific health history and contraceptive needs in private with a healthcare provider.” J.A. 1184; *see, e.g.*, J.A. 1222, 1167. As the IOM Report adopted by the Agencies recognized, “[e]ducation and counseling are important components of family planning services because they provide information about the availability of contraceptive options, elucidate method-specific risks and benefits for the individual woman, and provide instruction in effective use of the chosen method.” J.A. 432. In the Rules, the Agencies note only that “[s]ome commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling,” J.A. 21. They focus only on the financial cost of losing coverage for contraceptive *methods*, failing entirely to examine how the inability to even discuss contraception will impact women.

Failure to address these significant comments is fatal to an agency’s defense. *Duncan*, 681 F.3d at 449.

F. The Agencies’ Regulatory Impact Analysis is Arbitrary and Capricious

Finally, the Rules are premised on faulty assumptions about their impact. And because the assumptions on which the Rules rely are faulty, the Rules have failed to articulate “a rational connection between the facts found and the choice made.” *State Farm*, 463 U.S. at 43.

The Agencies estimate that between 70,515 and 126,400 women will lose contraceptive coverage because of the Rules. J.A. 40–47, 89–92. Although nominally used to calculate the annual financial impact of the final Rules, the Agencies also use these figures to support their narrative that the Rules will have only a minimal impact. *E.g.*, J.A. 16 n.26, 71. But the Agencies reached their estimates by relying on a series of unsupported assumptions.

First, the Agencies exclude an entire class of people who may lose coverage. The Agencies assume that each individual policyholder has at least one dependent, J.A. 41, 91, and

⁹ The final Title X rules ultimately eschewed these proposed changes. *See supra* note 5.

acknowledge that the individual exemption extends “to family coverage covering the participant and his or her beneficiaries enrolled under the plan,” J.A. 33; *accord* J.A. 86. And any individual who objects to contraceptive coverage—whether under the individual exemption, because he or she shares a moral objection with his or her employer, or through self-employment—will cause his or her female dependents to lose coverage too. J.A. 44, 90, 2372. These dependents should have factored in the Agencies’ analysis, but did not.

Second, the Agencies assumed that, before the Rules, no more than 209 entities were using the Accommodation. J.A. 40. They made the same assumption in the interim Religious Rule. J.A. 123. But in the interim Religious Rule, the Agencies used data from 2017 to estimate 1,027,000 employees and beneficiaries were covered by insurance plans from 209 those entities. J.A. 124–126. In the final Religious Rule, however, the Agencies use data from 2017 to estimate that 2,907,000 employees and beneficiaries were covered by accommodated insurance plans. J.A. 42. Assuming, as the Agencies do, *see* J.A. 41, that each policyholder has only one dependent, the data the Agencies’ have relied on suggests that those 209 employers employed on average 7,000 more people in 2017 than they did in 2015. That absurdity reveals the irrationality of the Agencies’ assumption, and they fail to provide any explanation—let alone a reasoned one—for this significant shift.

Third, the Agencies assume without any basis that the majority of people currently working for an accommodated employer will not lose contraceptive coverage. They speculate that 100 of the 209 entities using the accommodation will continue to do so in spite of the new exemptions, and that these 100 employers employ 75% of all people covered by accommodated plans. J.A. 41–42. Both assumptions are premised on religious hospitals continuing to use the Accommodation instead of the exemption. J.A. 42. For that assumption, the Agencies explain

only that, when the Accommodation was the only option, some religious hospitals stated they did not oppose using it. J.A. 41. But the Agencies point to no employer who commented or otherwise committed to continue using the Accommodation once the exemption becomes available. Given how the Agencies view the religious liberty interests at stake, there is no reason for them to discount that many employers that used the Accommodation will opt instead for the exemption, which would impact at least 256,025 women.¹⁰

Finally, even after deflating the number of women who may be affected in those three ways, the Agencies cut the estimated maximum of women that the Religious Rule would affect by two-thirds. To calculate the maximum number of women the rule will affect, the Agencies first marched through sourced statistics to estimate that 379,000 women of childbearing age who use contraception work for an employer that: (1) is eligible for the Religious Rule's exemption, (2) may actually have a religious objection to arranging for contraceptive care, (3) did not voluntarily cover contraception before the Guidelines guaranteed that coverage, (4) does not use a self-insured church plan, and (5) is not already exempt under the Church Exemption. J.A. 43–45. For the third condition—whether the employer covered contraception before that coverage was required—the Agencies relied on survey data in which 6% of respondents did not provide contraceptive coverage before the Guidelines and 31% of respondents were unsure of their past practices. J.A. 44. The Agencies used the 6% figure for its calculations—leading to a significantly lower estimate of effected women—because, the Agencies reasoned, a respondent that was unsure whether it covered contraception before the Guidelines was unlikely to have a

¹⁰ That figure reflects that of the 2,907,000 people covered under accommodated insurance plans, 20.2% of them are women of childbearing age, of which 43.6% use contraceptive covered under the Guidelines. J.A. 46 & n.116.

sincere religious objection to contraception, and thus unlikely to make use of the Religious Rule's exemption. J.A. 44 n.103.

After determining that 379,000 women work for an employer reasonably likely to use the exemption, the Agencies then reduced the estimate by two-thirds. J.A. 45. The Agencies assumed that many of the employers that had not provided contraceptive coverage before the Women's Health Amendment, but had done so since, would continue to provide that coverage. *Id.* That conclusion, in turn, reflected speculation that, of the employers that had not covered contraception before the Guidelines, most failed to do so for reasons other than religious objections to contraception. J.A. 45–46. But the Agencies already baked that assumption into their estimates by using 6% for the rate of employers that had not provided contraception before the Guidelines precisely because that low number captured only the employers “likely to have omitted such coverage on the basis of religious beliefs.” J.A. 44 n.103. Thus, the Agencies twice used the same fact to discount how consequential the Religious Rule will be.

For the Moral Rule, the Agencies entirely neglected to conduct this analysis, apparently assuming (without saying so) that no employer pre-ACA declined to offer contraceptive coverage for moral reasons. J.A. 92.

In total, the Agencies' assumptions, omissions, and arbitrary speculations render their economic assessment of the Rules arbitrary and capricious.

II. The Religious Rule Violates the Establishment Clause

The Establishment Clause of the First Amendment provides that “Congress shall make no law respecting an establishment of religion.” U.S. Const. amend. I. When the government acts to accommodate religion, as it has here, the Establishment Clause operates as ceiling on how far the government may go. First, the government may not pass the threshold at which “accommodation may devolve into ‘an unlawful fostering of religion.’” *Corp. of Presiding Bishop of Church of*

Jesus Christ of Latter-day Saints v. Amos, 483 U.S. 327, 334–35 (1987) (quoting *Hobbie v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. 136, 145 (1987)). Second, because “[t]he First Amendment . . . gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities,” *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 710 (1985), any accommodation of religious interests “must be measured so that it does not override other significant interests,” *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005). Adhering to these reasonable limits is what saves government’s accommodation of religious interests from being constitutionally infirm. For example, the Court rejected an Establishment Clause challenge to the Religious Land Use and Institutionalized Persons Act (RLUIPA), a statute that operates much like RFRA, because “applying RLUIPA, courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries.” *Cutter*, 544 U.S. at 720; *see also. Hobby Lobby*, 573 U.S. at 729 n. 30.

The Supreme Court’s decision in *Caldor* most instructively displays these principles. There, a department store challenged a Connecticut statute that provided all employees with the right not to work on their chosen Sabbath day. 472 U.S. at 708. The Supreme Court held that the Connecticut statute, by providing “Sabbath observers with an absolute and unqualified right not to work on whatever day they designate as their Sabbath” violates the Establishment Clause. *Id.* at 709. The Court noted that the State impermissibly “commands that Sabbath religious concerns automatically control over all secular interests at the workplace; the statute takes no account of the convenience or interests of the employer or those of other employees who do not observe a Sabbath.” *Id.* Plus, the statute provided no exception for “when the employer’s compliance would require the imposition of significant burdens on other employees required to work in place

of the Sabbath observers,” and the statute “allows for no consideration as to whether the employer has made reasonable accommodation proposals.” *Id.* at 710.

Just the same, the Religious Rule permits any employer who objects to providing contraceptive to interfere with their employees’ access to contraception, granting an absolute right to inflict concrete harms to another. That is because the exemption results in the loss of contraceptive coverage without cost sharing. By the Agencies’ tally, the new exemption will cost up to “126,400 women of childbearing age who use contraceptives” coverage for contraception without cost sharing. J.A. 15. And the employers’ unyielding right to strip their employees of access to contraceptive coverage fails to account for the hardships imposed on the non-believing employees who lose this vital health care coverage. As in *Caldor*, the religious beliefs of one party prevail, without any consideration of the severity of that resulting harm. *See also Cutter*, 544 U.S. at 710 (“An accommodation must be measured so that it does not override other significant interests.”); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (plurality op.) (religious accommodations are permissible when they do not “impose substantial burdens on non-beneficiaries”).

The Agencies reject that the Religious Rule allows employers to inflict any harm. By their telling, the Religious Rule only relieves a governmental burden that would not exist but for the Guidelines’ inclusion of contraception. J.A. 14. That women receive contraceptive coverage because of the Guidelines rather than some other source of law is immaterial to the harm that the Religious Rule permits. The Guidelines, both before and after the Religious Rule, impose a general requirement that group insurance plans cover contraception. Because of the Religious Rule, and the Religious Rule alone, up to “126,400 women of childbearing age who use

contraceptives” will no longer have access to medical coverage that the law otherwise entitles them to receive without cost sharing.

Worse, the Agencies have at their disposal an alternative to the exemption that, for many of the employers that may now claim the exemption, fully resolves any cognizable burden under RFRA while still allowing access to contraception without cost sharing. Although the Agencies insist that the availability of the Accommodation is irrelevant for purposes of evaluating the Religious Rule under RFRA, J.A. 10, the availability of the Accommodation certainly matters for evaluating the Religious Rule under the Establishment Clause. Extending the exemption to entities for which the Accommodation would have resolved any conflict with RFRA confers a gratuitous religious benefit for which there is no explanation other than preferring religious interests.

At bottom, then, the Religious Rule impermissibly favors religious employers over their employees who do not share their religious beliefs, and it does so in a manner that goes well beyond mere accommodation. The Religious Rule grants an unqualified right to religious employers that imposes significant hardships on their employees in violation of the Establishment Clause.

III. The Rules Create an Unreasonable Barrier to the Availability of Appropriate Medical Care in Violation of Section 1554 of the ACA

Section 1554 of the ACA prohibits the Secretary of HHS from “promulgat[ing] any regulation that ... creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care.” 42 U.S.C. § 18114(1). By allowing employers to deny women access to contraceptive care, the Rules do exactly that.

Contraception is, for many women, “appropriate medical care.” *See supra* Background Part I. Indeed, according to HRSA, contraception is among the preventive services “necessary

for women’s health and well-being,” *See* J.A. 312-A. And since the Rules allow employers to deny women coverage for contraception, they “create[] . . . barriers” for women who wish to access such care. That some women denied coverage may be able to surmount these barriers and obtain contraception elsewhere (often at a significantly higher cost) does not change that by allowing employers to deny coverage, the Rules make it more difficult for women to access the care they need.

Those barriers are “unreasonable” as well. In many cases, if not all, the exemption is not needed to resolve the religious or moral interests it ostensibly addresses. Nor did the Agencies try to find a way to accommodate the concerns of religious objectors “while at the same time ensuring that women covered by petitioners’ health plans ‘receive full and equal health coverage, including contraceptive coverage.’” *Zubik*, 136 S. Ct. at 1560–61. The unreasonableness of the Rules is compounded by the Agencies’ failure to address significant concerns raised by commenters, and the Agencies’ inexplicable about-face on fundamental questions such as the safety and efficacy of contraception. *See supra* Parts I.C & I.E.

As a result, the Rules create “unreasonable barriers to the ability of individuals to obtain appropriate medical care,” and are therefore unlawful under the ACA and the APA.

IV. The Rules Violate the Equal Protection Provisions of the Fifth Amendment

The Rules also violate the Constitution’s guarantee of equal protection, a guarantee applied to the Federal Government through the Fifth Amendment. Under the Fifth Amendment, classifications based on gender are subject to heightened scrutiny. *See Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1689–90 (2017); *see also Abdul-Akbar v. McKelvie*, 239 F.3d 307, 317 (3d Cir. 2001) (“Fifth Amendment equal protection claims are examined under the same principles that apply to such claims under the Fourteenth Amendment.”). Successful defense of such a classification “requires an ‘exceedingly persuasive justification’”—the government must

demonstrate “at least that the challenged classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives.” *Morales-Santana*, 137 S. Ct. at 1690 (citations and internal quotation marked omitted). This is a demanding burden. *United States v. Virginia*, 518 U.S. 515, 533 (1996).

The Rules at issue here target women for uniquely unfavorable treatment. Although the ACA requires coverage for many different types of preventive services, the Rules single out care for women’s reproductive health for lesser protection. Doing so falls in line with the Executive Order that inspired the Rules. Although that Executive Order purported to be concerned with conscience issues generally, the only regulatory provision explicitly mentioned in the Executive Order, and then in the Final Rules, is the Women’s Health Amendment.

Because the Rules discriminate, the Agencies must have an “exceedingly persuasive justification” for allowing conscience protections to categorically deprive women of access to an essential healthcare benefit without cost sharing, while leaving undisturbed all other essential healthcare benefits to which an employer could have a religious or moral objection. That means the Agencies must answer why the Rules’ discriminatory focus is justified even though women’s health, education, and livelihoods depend on the ability to control reproductive choices; without that autonomy, women cannot participate as full and equal members of society. *Virginia*, 518 U.S. at 532 (women cannot be denied an “equal opportunity to aspire, achieve, participate in and contribute to society”); *Int’l Union v. Johnson Controls*, 499 U.S. 187, 211 (1991) (a woman’s reproductive and economic roles are her own choice, not that of the government or her employer).

The Rules’ treatment of women does not meet the “exceedingly persuasive justification” because the Agencies did not consider alternatives to allowing employers interference with

women's access to contraceptive coverage. And the protection afforded for an employer's moral objections to the provision of contraceptive services cannot provide an "exceedingly persuasive justification" for overriding Congress' decision to provide essential healthcare benefits to women. The Moral Rule does not define what moral objections qualify, leaving open the possibility that an employer claims the exemption based on views that are themselves inherently and intentionally discriminatory. The Agencies cannot justify elevating all the undefined views that may qualify for the moral exemption over the health and societal benefits that contraception confer to women.

Moreover, even if this Court were to consider "conscience protections" to be an important governmental objective in the provision of healthcare generally, the Government cannot demonstrate that the *discriminatory* means employed here are "substantially related to the achievement of those objectives." The Government has failed to provide any justification for targeting only women's health care when purportedly protecting religious and moral conscience decisions. As the Seventh Circuit has noted:

[C]ontraceptive care is by no means the sole form of health care that implicates religious concerns. To cite a few examples: artificial insemination and other reproductive technologies; genetic screening, counseling, and gene therapy; preventative and remedial treatment for sexually-transmitted diseases; sex reassignment; vaccination; organ transplantation from deceased donors; blood transfusions; stem cell therapies; end-of-life care, including the initiation and termination of life support; and, for some religions, virtually all conventional medical treatments.

Grote v. Sebelius, 708 F.3d 850, 866 (7th Cir. 2013). While the Agencies' answer may be that some lines must be drawn because an insurance system in which each individual or employer can demand an insurance policy that conforms to his or her religious beliefs is unworkable, that limitation cannot justify the Government's decision to allow employers to interfere with essential healthcare benefits for *women only*.

In sum, the Women’s Health Amendment was intended to ensure that women receive essential healthcare coverage on an equal basis with men. The Agencies violated women’s equal protection rights when they targeted the essential healthcare benefits that the ACA afforded women while leaving all other essential health benefits intact.

V. The Rules Violate Section 1557 of the ACA and Title VII of the Civil Rights Act

For similar reasons, the Rules violate two federal statutes that prohibit discrimination on the basis of sex: Section 1557 of the ACA and Title VII of the Civil Rights Act.

Section 1557 prohibits “discrimination under[] any health program or activity, any part of which is receiving Federal financial assistance,” on several grounds, including “the ground prohibited . . . under title IX of the Education Amendments of 1972.” 42 U.S.C. § 18116(a). Title IX prohibits discrimination “on the basis of sex” in education, 20 U.S.C. § 1681, and its implementing regulations make clear that it prohibits discrimination on the basis of pregnancy. *See* 34 C.F.R. § 106.40(b)(1) (“A recipient shall not discriminate against any student . . . on the basis of such student’s pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom.”).

Similarly, Title VII prohibits employers from discriminating on the basis of sex. 42 U.S.C. § 2000e-2(a). In 1978, Congress enacted the Pregnancy Discrimination Act (PDA), which amended Title VII to clarify that discrimination because of “pregnancy, childbirth, or related medical conditions” is discrimination on the basis of sex. *See* 42 U.S.C. § 2000e(k). The PDA corrected the Supreme Court’s earlier, erroneous interpretation of Title VII in *General Electric Co. v. Gilbert*, 429 U.S. 125 (1976), and expressly embraced the logic of the dissenters in that case, *see* H. Rep. No. 95-948, at 2 (1978) (“It is the Committee’s view that the dissenting justices correctly interpreted the [Civil Rights] Act.”); *see also Newport News Shipbuilding and Dry Dock Co. v. EEOC*, 462 U.S. 669, 676–82 & n.17 (1983).

General Electric involved a challenge to a company rule that provided employees with disability benefits but specifically excluded disabilities related to pregnancy. *See* 429 U.S. at 125. In dissent, Justice Stevens observed, “[b]y definition, such a rule discriminates on account of sex; for it is the capacity to become pregnant which primarily differentiates the female from the male.” *Id.* at 161–62. In passing the PDA, Congress embraced that discrimination on the basis of sex-based characteristics is discrimination on the basis of sex. *See* H. Rep. No. 95-948, at 2 (quoting Stevens dissent with approval); *see also Newport News*, 462 U.S. at 676 (“Accordingly, we shall consider whether Congress, by enacting the Pregnancy Discrimination Act, not only overturned the specific holding in *General Electric v. Gilbert*, but also rejected the test of discrimination employed by the Court in that case. We believe it did.”).

Relying on this same principle, the Supreme Court subsequently struck down, in *U.A.W. v. Johnson Controls, Inc.*, an employer’s policy that excluded women, except those determined to be infertile, from jobs involving exposure to lead. *See* 499 U.S. 187, 199 (1991). By targeting “women with childbearing capacity,” the policy violated Title VII’s prohibition on sex discrimination. *See id.* at 200. The Court noted that its conclusion was “bolstered by” the PDA, finding that by using “the words ‘capable of bearing children’ ... as the criterion for exclusion, [the employer] explicitly classifies on the basis of potential for pregnancy.” *Id.* at 199. And the Court concluded, “[u]nder the PDA, such a classification must be regarded, for Title VII purposes, in the same light as explicit sex discrimination.” *Id.*

The same logic prohibits employer from treating contraception differently than analogous categories of health care. For example, if an employer provides prescription drug coverage to its employees, it cannot exclude contraceptive prescriptions without running afoul of Title VII. *See Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266, 1269 (W.D. Wash. 2001) (“In light of the

fact that prescription contraceptives are used only by women, [defendant's] choice to exclude that particular benefit from its generally applicable benefit plan is discriminatory.”). *But see In re Union Pac. R.R. Employment Practices Litigation*, 479 F.3d 936, 942 (8th Cir. 2007). As the *Erickson* opinion recognized, “when an employer decides to offer a prescription plan covering everything except a few specifically excluded drugs and devices, it has a legal obligation to make sure that the resulting plan does not discriminate based on sex-based characteristics and that it provides equally comprehensive coverage for both sexes.” *See Erickson*, 141 F. Supp. 2d. at 1272. Thus, treating contraceptive benefits differently than other preventive services is unlawful because it discriminates on the basis of “sex-based characteristics,” *see id.*, and because it violates Congress’s expressed intent that the PDA’s protections should “extend[] to the whole range of matters concerning the childbearing process.” *See* H. Rep. No. 95-948, at 5.

Despite these statutes, the Rules authorize differential treatment. An employer that refuses to provide contraceptive care for women will still have an obligation to provide other preventive care, *see* 42 U.S.C. § 300gg-13(a)(1); *id.* § 18022(b)(1)(F), and will similarly have an obligation to provide prescription benefits, *see id.* § 18022(b)(1)(I). Section 1557 and Title VII each prohibit such discrimination, and the Rules, by authorizing that discrimination anyway, are unlawful under the APA. *See* 5 U.S.C. § 706(2)(A); *see also Farrington v. Johnson*, 206 F. Supp. 3d 634, 635, 644 (D.D.C. 2016) (refusing to dismiss APA claim arising under Title VII); *Pima Cty. Cmty. Coll. Dist. v. EEOC*, No. 75-210, 1976 WL 548, at *2 (D. Ariz. 1976) (observing that Title VII is “certainly a relevant statute within the contemplation” of the APA). And even if differential treatment for contraception was not discrimination because of a sex-based characteristic, contraceptive use is part of “the whole range of matters concerning the

childbearing process.” Either way, differential treatment of contraceptive care violates federal anti-discrimination statutes.

The Rules tried to get ahead of this problem, insisting that any way in which the Rules specifically disadvantage women is a product of the Women’s Health Amendment, which separates women’s health for differential treatment. J.A. 16, 71. But that argument does not work. The Women’s Health Amendment is just one part of a package of preventive services that Congress has required group health plans cover without cost sharing. Under the ACA, group insurers must cover all preventive services recommended for men and women alike. 42 U.S.C. § 300gg-13(a)(1)–(4). The Rules, however, apply to a class of preventive services that only women use. Therefore, by authorizing employers and other plan sponsors to exclude contraception, the Rules authorize discrimination on the basis of sex, and are therefore unlawful under the APA.

VI. The Rules Must be Vacated

A reviewing court shall “hold unlawful and set aside” agency action that is “contrary to law” or otherwise violates the requirements of the APA. 5 U.S.C. § 706(2). This section requires that the Rules here be vacated; the Supreme Court said as much last term. *See Dep’t of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1916 n.7 (2020) (explaining Court had no need to “examine the propriety of the nationwide scope of the injunctions” against DACA recession memo because Court was affirming a separate order vacating the same memo); *see also Pennsylvania*, 930 F.3d at, 575 , *rev’d and remanded on other grounds*.

Although some courts have recognized circumstances under which rules that violate the APA should be remanded without vacatur, “neither the Supreme Court nor the Third Circuit has held that the APA permits a court to remand an invalid regulation without first vacating the

regulation.” *Comite de Apoyo a los Trabajadores Agricolas v. Solis*, 933 F. Supp. 2d 700, 714 (E.D. Pa. 2013); *see also Council Tree Commc’ns, Inc. v. F.C.C.*, 619 F.3d 235, 258 n.13 (3d Cir. 2010) (“express[ing] no view as to whether [the court is] authorized to order” remand without vacatur).¹¹ Rather, “Section 706(2)’s seemingly mandatory language” requires vacatur if agency action violates the requirements of that section. *Comite de Apoyo*, 933 F. Supp. 2d at 714.

Even if this court were authorized to consider other remedies upon a finding of an APA violation, vacatur is appropriate here. The deficiencies of the Rules are “serious,” and could not be easily corrected on remand. *See Council Tree*, 619 F.3d at 258 (relying on “seriousness” of APA violations in concluding “even assuming we have the authority to remand the matter without vacatur, we would decline to do so here.”). This Court has on two previous occasions concluded that the harms from the Rules were serious enough to warrant the “extraordinary remedy,” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008), of a preliminary injunction. *See* 351 F. Supp. 3d at 827–30; 281 F. Supp. 3d at 581–85. Those findings remain valid today. *Cf. City of Philadelphia v. Sessions*, 309 F. Supp. 3d 289, 340 (E.D. Pa. 2018), *aff’d in part, vacated in part sub nom. City of Philadelphia v. Attorney Gen. of United States of Am.*, 916 F.3d 276 (3d Cir. 2019) (“The Court’s finding of irreparable injury from the preliminary injunction stage remains equally applicable at the permanent injunction stage.”) (cleaned up).

¹¹ *Council Tree* did note that the agency defendant had “cite[d] to a case in which [the Third Circuit] remanded without vacatur, albeit without commenting on the issue.” 619 F.3d 235, 258 n.13 (citing *Am. Iron & Steel Inst. v. EPA*, 568 F.2d 284, 310 (3d Cir. 1977)).

CONCLUSION

For the reasons set forth above, the States' Motion for Summary Judgment should be granted and the Rules vacated.

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